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## Croatia

## Biotechnology

## Status of Biotech Regulations

**2003**

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**Report Highlights:**

Over the past five months, several pieces of legislation regulating the importation, cultivation and marketing of biotech crops and foods have been passed in Croatia. Many provisions of these laws are still not in force and thus it is difficult to state definitively how they will function in practice. This reports provides an overview of the current regulatory environment for biotechnology and includes contact information for the Ministries and Agencies that monitor and/or enforce biotech regulations.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Vienna [AU1]  
[HR]

## **Status Of Croatian Biotech Regulations**

### **Entry Into Force**

Over the past five months in Croatia, several pieces of legislation regulating the importation, cultivation and marketing of biotech crops and foods have been passed. Many provisions of these laws are still not in force and thus it is difficult to state definitively how they will function in practice.

The Law on Consumer Protection was the first biotech- related law to be passed. It was published in the government gazette, number 96/03 on June 10, 2003, after being approved May 29. The Food Act was approved by Parliament on July 14 and published in government gazette number 117 on July 23. The third law that passed Parliament (03/09/03) is the Law on Protection of Nature (not yet published in the government gazette). Since we still do not have this law's actual text, this cable was compiled on the basis of the final draft that went to parliamentary procedure. According to newspapers and governmental sources, the amendments made to the final text deal only with the restriction of GMO planting in national parks, nature parks, and other protected zones, as well as in areas intended for ecological agriculture and tourism.

Normally laws enter into force eight days after being published in the government gazette. The Consumer Protection law was applied 90 days (enforced 8 days) after being publishing (it is unclear to us the difference being "being in force" and "application," but these two periods are laid out in the law). Provisions on product labeling from the Consumer Protection Law will be regulated by sub-laws. Until they are enacted, the old provisions from the Law on Norms will be applied as long as they do not contradict the Law on Consumer Protection.

Articles 29, 74 (section 4), and 75 of the Food Law will be applied at the latest three years after the law came into force. Article 29 deals with introduction of HACCP in food handling and processing facilities. Articles 74 (section 4) and 75 deal with authorized testing laboratories and reference laboratories for official food control.

### **Regulatory Process**

The Law on Protection of Nature is the overarching law for biotechnology issues and, together with the Food Law and future sub-laws, regulates the importation, transshipment, production, usage, and sale of products of agricultural biotechnology (all food, feed and seed). To import agricultural biotechnology products into Croatia, the importer must, according to the Law on Protection of Nature, have a permit for limited usage or intentional introduction into the environment before placing the product on the market. "Limited usage" is only relevant for trials and will not be considered in detail in this cable.

### **Procedure for obtaining a permit for intentional release into the environment**

To introduce a GMO into the environment, a permit from the Ministry of Environment is needed, as well as the consent of the Ministry of Agriculture. Before applying for a permit, a risk assessment study by an authorized company is mandatory (though existing risk assessment studies from other sources may be used, with the source's written consent).

The Minister of the Environment, with the consent of the Minister of Agriculture, will specify in special regulation the content, scope, and methodology of these risk assessments, as well as the companies authorized to perform the assessment studies. Before introducing the GMO into the environment, a contingency plan (in case of uncontrolled spreading of the GMO) is also required. The government will outline the approximate contents and application

plan of these measures. The permit application must contain: technical documentation with prescribed parts, a risk assessment, contingency plan, and other relevant data. The Minister of the Environment will describe, in a special regulation with consent of the Minister of Agriculture, how to apply for a permit, and contents of the permit application. The Ministry of Environment, with consent of Ministry of Agriculture, will issue the permit within 90 days of receiving the application. Permits may be issued in an abbreviated procedure if there is enough information and experience about releasing the particular GMO into the environment. In that case, the permit can be issued within 30 days.

### **Procedure For Obtaining A Permit For Placing Product Onto The Market**

Any GMO placed on the market for the first time requires a special permit. The permit is issued for a maximum of 5 years, but is renewable. Permits for products used in agriculture, forestry and fishery are issued by an agency of the Ministry of Agriculture, with the consent of the Ministry of Environment. Permits for foodstuffs are issued by an agency of the Ministry of Health, with the consent of the Ministry of Agriculture. Before applying for a permit, a risk assessment study is mandatory. The Minister of the Environment with the consent of the Minister of Agriculture and the Minister of Health will prescribe the contents and scope of the risk assessment study, to be laid out in a special regulation. Each application must contain technical documentation, a risk assessment study, conditions of placing the product on the market, a monitoring plan, a time-span proposal for the permit, a labeling proposal, a packaging proposal, and a summary of technical documentation. Another permit must be obtained for each additional application of approved GMOs. The Minister of the Environment, with the consent of the Minister of Agriculture and Minister of Health, will describe the required contents of the application and technical documentation, and the conditions of monitoring, labeling and packaging, in a special regulation. If placing the product on the market causes intentional or unintentional introduction of GMOs into the environment, a copy of the application will go to the Board for Introduction of GMOs into the Environment. If food or feed will be placed on the market a copy of the application will go to the Board for Novel Food and Feed. These boards must report back within 60 days of receiving the application.

Additionally, the Food Law requires that all novel foods introduced into the market be approved by the Minister of Health in agreement with the Minister of Agriculture, based on the previously obtained scientific expert statement of the Croatian Food Agency. The conditions and the procedure for issuing the approval shall be provided by the Minister of Health in cooperation with the Minister of Agriculture.

### **Enforcement**

The following Ministries and Agencies monitor and/or enforce the mentioned laws:

Ministry of Environmental Protection and Spatial Planning (Ministry of Environment)  
Contact: Roko Andricevic  
Assistant Minister for Environmental Protection Grada Vukovara 78 10 000 Zagreb  
tel. 00385 1 6106 556 fax 00385 1 6116 388  
Email: zastita-okolisa@mzopu.hr

Ministry of Health  
Contact: Croatian Institute for Public Health  
Krunoslav Capak Rockefeller 7 10 000 Zagreb  
tel. 00385 1 468 3007

Ministry of Agriculture and Forestry (Ministry of Agriculture)

Contact: Miroslav Bozic

Assistant Minister for Agricultural Policy and Rural Development Vukovarska 78 10 000  
Zagreb  
tel. 00385 1 6106 111 fax. 00385 1 6109 206

Croatian Food Agency  
Not yet established.

State Inspectorate

### **Law on Protection of Nature**

Oversight will be done by environmental protection inspectors, sanitary inspectors, veterinary inspectors, agricultural inspectors, plant protection inspectors, state inspectorate inspectors, etc. The testing laboratory will be established by the Ministry of Health with support from the Ministry of Agriculture and the Ministry of Environmental Protection.

Company penalties for violating the biotech provisions of the Law on Protection of Nature will range from Kn 100,000 to Kn 1,000,000 depending on the violation, with responsible employee penalties from Kn 15,000 to Kn 70,000.

### **Food Law**

Oversight is done by sanitary inspectors, border sanitary inspectors, veterinary inspectors, border veterinary inspectors and other state officials who are authorized by a competent Minister.

Company penalties for violating the "novel food" provisions of the Food Law concerning placing novel food on the market or labeling (see below) will be from Kn 100,000 to Kn 500,000, with each responsible individual fined from Kn 5,000 to Kn 10,000.

### **Consumer Protection Law**

Oversight (see below on labeling) is done by the State Inspectorate and other designated inspectors.

Manufacturer or trader penalties for releasing incorrectly labeled (or unlabeled) product on the market will range from Kn 50,000 to Kn 100,000 and each responsible employee will be penalized from Kn 3,000 to Kn 5,000.

The current exchange rate is approximately \$1 = Kn 6.5.

### **Shipments of Biotech Products**

Shipments of agricultural biotech products should be tested in the newly opened biotechnology-testing laboratory. This laboratory is not yet testing samples because there are still no specific regulations specifying what tests should be done. Thus, for the moment, agricultural biotechnology products can enter Croatia undetected. But there are indications that testing will start soon.

### **Traceability System**

Traceability as mentioned in the Food Law deals not only with biotech products. It is a system for all levels of production, processing and distribution of foodstuffs, raw materials of vegetable and animal origins, food-producing animals or animals used in food production, which includes the tracing of any other sort of material intended for incorporation (or which shall be incorporated) into food. Food business operators must establish a record keeping system of their suppliers and customers. Food placed on the market must be identified by specific documentation or other information.

The Law on Protection of Nature requires that all agricultural biotechnology products have documentation indicating the product as a GMO or containing GMOs, and a correct code that is given to a particular GMO. All companies that place GMOs or products containing GMOs on the market must keep a database and have a procedure enabling the identification of companies from which the product was obtained or to which it was sold, for five years after it was placed on the market (excluding end consumers).

### **Documentation**

For agricultural products that may contain the products of agricultural biotechnology, special documentation is needed. Documentation is the same as for 100 percent agricultural biotechnology products. Unfortunately, there are no specifications yet because regulations that should outline documentation are still unpublished.

### **In-country Field Tests**

In-country field tests are not required prior to regulatory approval of a biotech crop by current legislation (see previous text).

### **Biotech Approvals**

A complete list of the information required by the government for biotech crop application consideration (under the Law on Protection of Nature, see the procedure for obtaining a permit for intentional release into the environment) is: technical documentation with specific parts (data about the applicant; data on GMO; data on conditions of environmental release; data on interaction of GMO and environment; monitoring program; data on methods of supervision over release of GMO; data on handling GMO waste; summary of technical documentation), risk assessment of GMO introduction in environment, contingency plan (in case of uncontrolled spread of GMO in environment), and other relevant data.

### **Labeling**

Food and feed containing agricultural biotechnology products must be labeled according to the Food Law, the Law on Protection of Nature and the Consumer Protection Law. The threshold is still undetermined, but under the Law on Protection of Nature, in cases where coincidental and technologically unavoidable traces of permitted GMO are found, the government can determine the threshold below which the products need not be labeled.

According to the Food Law, food and feed labels should have additional special information to keep consumers informed about any ways in which the novel food or its ingredients no longer corresponds to the existing food or food ingredient. In that case, the declaration must contain information about the changed characteristics or features, including the method used to produce that indication or characteristic. The food and food ingredients containing (or consisting of) GMOs must have a visible indication that it contains or consists of GMOs. The indication must clearly state "genetically modified organisms" or contain the sentence "this

product contains genetically modified organisms." Food and food ingredients originating from GMOs but not containing them must have a visible indication that they originate from GMOs.

The requirements regarding the declaration of novel food under the Food Law will be provided for by a regulation developed by the Minister of Health in accordance with the Minister of Agriculture and Forestry within one year from enactment of the Law.

According to the Law on Protection of Nature, any agricultural biotechnology product placed on the market must have a visible mark on its package and accompanying documentation stating that the product is a GMO or contains GMOs. This label should clearly say "genetically modified organism" or contain the sentence "this product contains genetically modified organisms."

The Consumer Protection Law establishes minimum product labeling requirements, which manufacturers should use to identify transformed products, including transformed ingredients and supplements, as well as the type of transformation, in accordance with special regulations. It is unclear if this is a reference to the Food Law (generally considered to be the main legislation on labeling), or subsequent implementing regulations for the Consumer Protection Law. The designated Minister (depending on the product) will establish the detailed content of the label, in concert with other Ministries and laws (such as the Food Law) and regulations.

### **Extent of Labeling**

It could be said that all levels of food products (i.e. processed and unprocessed) must carry a label.

### **Other Labeling**

USDA is unaware of any laws or regulations governing the use of labels such as "biotech-free," "non-biotech," "GMO-free," or "non-GMO."